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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/619,901

07/19/2000

Michael J. Botich

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09/11/2002

DANN DORFMAN HERRELL & SKILLMAN
SUITE 720
1601 MARKET STREET
PHILADELPHIA, PA 19103-2307

EXAMINER

SERKE, CATHERINE

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 09/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/619,901

Applicant(s)

BOTICH ET AL.

Examiner

Catherine Serke

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 recites the limitations "the end", "the rearward end" and "the biasing element" in lines 14, 15 and 18. There is insufficient antecedent basis for these limitations in the claim.

Claims 46 and 52 recite the limitations "The needle device" and "the biasing element" in the preamble and in line 2-3, respectively. There is insufficient antecedent basis for these limitations in the claim.

Claims 47 and 53 recite the limitations "The needle device" in the preamble, "the biasing element" in lines 3 and 7 and "said predetermined portion" in line 5. There is insufficient antecedent basis for these limitations in the claim.

Claims 48 and 54 recite the limitation "the connection" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 50 and 56 recite the limitations "the rest" in line 1 and "the rearward end" in line 2. There is insufficient antecedent basis for these limitations in the claim.

Claim 51 recites the limitations "the end" in lines 8 and 16, "the rearward end" in line 14 and "the biasing element" in line 17. There is insufficient antecedent basis for these limitations in the claim.

Claim 57 recites the limitation "the end" in line 14. There is insufficient antecedent basis for this limitation in the claim.

Claims 61 and 62 recite the limitation "the rearward end" in lines 3 and 2, respectively. There is insufficient antecedent basis for this limitation in the claim.

Claim 63 recites the limitation "the barrel" in line 11. There is insufficient antecedent basis for this limitation in the claim.

Claims 67 and 68 recite the limitation "the rearward end" in lines 3 and 2, respectively. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 45-48, 50-54, 56-58, 60-64 and 66-68 are rejected under 35 U.S.C. 102(e) as being anticipated by Villen Pascual (US Pat# 5,049,133).

Villen Pascual discloses a single use safety syringe having a needle (2) operable between a projected position and a retracted position (see figures 1 and 2), a housing (1) having a fluid cavity, a plunger (11) with a cavity (17), a biasing element spring (9) and a needle hub assembly (4,5,14) with a needle retainer/connector (8). The plunger has a frangible cover (12). The needle retainer has resilient fingers (8) that are spread during forward displacement of the plunger into the termination position to allow for retraction of the needle due to the expansive force of the spring. The housing and needle assembly are connected via the lodging (3) at the distal end of

the barrel and the needle hub (4) of the needle assembly. This is a frictional connection and therefore is a releasable connection. The device further includes a lock mechanism in the form of a ring projection on the plunger tip (15) and a groove in the internal cavity at the distal end of the housing (16). The method steps, while not specifically disclosed, are considered inherent in order to perform the proper function and use of the device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 49, 55, 59 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Villen Pascual in view of Jagger et al (4,592,744), Alberts et al (4,906,236), Paris (4,911,693) or Ridderheim et al (4,955,870).

Villen Pascual meets the claim limitations as described above but fails to include the two connectors being a threaded connection.

Jagger, Alberts, Paris and Ridderheim all disclose hypodermic syringes with needle assemblies that are connected to the syringe housing via a threaded connection or connector. See Figs 4-6 (Jagger); Figs 3-4 (Alberts); Figs 2-4 (Paris); and Fig 3 (Ridderheim).

At the time of the invention, it would have been obvious to incorporate the threaded connection of Jagger, Alberts, Paris or Ridderheim into the invention of Villen Pascual. Threaded connections and luer-lock mechanisms (female male thread connector) are well known in the art and used to impart adaptability into syringes. Motivation for incorporation of the

threaded connector would have been in order to enhance the ability of the technician to quickly change needle gauges without having to get another syringe.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45-68 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3,6,11-12,19-20 and 23-24 of U.S. Patent No. 5,407,431; claims 1-2,4-11, of U.S. Patent No. 6,096,005; claims 1-3,12,15-20 and 23-24 of U.S. Patent No. 5,188,599 and claims 1-3,6,12 and 15-16 of U.S. Patent No. 4,994,034.

Although the conflicting claims are not identical, they are not patentably distinct from each other because, *inter alia*, the instant invention and the parent patents all teach a retractable syringe that includes the mechanism of retracting a needle through a frangible cover and into a cavity in the plunger. The needle is retracted through the expansive force of a spring and the plunger is locked into place.

Terminal Disclaimer

The person who signed the terminal disclaimer has failed to state his/her capacity to sign for the corporation or other business entity, and he/she has not been established as being authorized to act on behalf of the assignee.


The person who signed the terminal disclaimer is not recognized as an officer of the assignee, and he/she has not been established as being authorized to act on behalf of the assignee. See MPEP § 324.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine Serke whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine Serke 
September 4, 2002


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700